EXHIBIT A

510(k) Premarket Notification Database

Device Classification Name	Mouthguard
510(K) Number	K053580
Device Name	DOCTOR'S NIGHTGUARD
Applicant	DENTAL CONCEPTS LLC. 555 Thirteenth Street, Nw Washington, DC 20004
Contact	Howard M Holstein
Classification Product Code	MQC
Date Received	12/22/2005
Decision Date	03/03/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 4/05/2007

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2003

Dental Concepts LLC
C/O Mr. Michael Lesser
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K024261
Trade/Device Name: Bite Plate
Regulation Number: None
Regulation Name: Dental Protector
Regulatory Class: Unclassified
Product Code: MQC
Dated: March 5, 2003
Received: March 6, 2003

Dear Mr. Lesser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

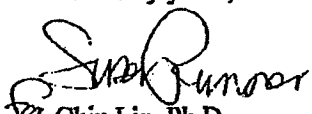
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K053580

Device Name: Doctor's® NightGuard™

Indications for Use:

The Doctor's NightGuard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Prescription Use ____ AND/OR Over-The-Counter Use__X_
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

[illegible] General Hosp[illegible]
[illegible] Dental Devices

K053580

Page ___ of ___

K053580

MAR 3 2006

510(k) SUMMARY

Dental Concepts The Doctor's® NightGuard™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Hogan & Hartson, LLP
555 13th Street, N.W.
Washington, D.C. 20004

Contact: Howard M. Holstein

Phone: (202) 637-5600
Facsimile: (202) 637-5910

Date Prepared: December 22, 2005

Name of Device and Name/Address of Sponsor

Doctor's® NightGuard™

Dental Concepts, LLC
650 From Road
Paramus, NJ 07652

Contact Person: Michael Lesser, President
Phone: (201) 225-2151
Facsimile: (201) 576-9780

Common or Usual Name

Dental Protector

Classification Name

Unclassified

Predicate Devices

Dental Concepts BruxGuard
Hollywood Products Mouth Peace
GEM Scientific Products, Inc. Tension Reliever

Intended Use / Indications for Use

The Doctor's NightGuard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Technological Characteristics

The Doctor's NightGuard is composed of a soft, formable clear upper material, made of ELVAX® resin, a copolymer of ethylene and vinyl acetate, and a hard occlusal base, which cushions the teeth. The base is composed of Elvaloy®, a copolymer of ethylene and methyl acrylate containing 9% methyl acrylate. When heated and then briefly cooled, the upper material can be molded to fit the user's upper teeth. The hard base prevents bite-through by users with moderate to severe nocturnal bruxing. The shock absorbing polymer material cushions the teeth on all sides.

Performance Data

No performance data is required in support of this 510(k) notice.

Substantial Equivalence

The Doctor's NightGuard is as safe and effective as Dental Concepts' BruxGuard. The two devices are physically the same. The labeling for the Doctor's NightGuard has been revised to make it suitable for OTC use. Because the two devices are the same, the Doctor's NightGuard possesses the same technological characteristics and principles of operation and a similar intended use as the BruxGuard predicate device. The Doctor's NightGuard also has similar intended uses and indications as the Hollywood Products Mouth Peace and the GEM Scientific Products, Inc. Tension Reliever, which were sold over the counter, like the NightGuard. Thus, the Doctor's NightGuard is substantially equivalent.

EXHIBIT B

To: Kelly M. Kaplan
4 Woodmont Road
Upper Montclair, NJ 07043

GENERAL RELEASE

This General Release ("Release") is made and entered into by and between Dental Concepts, LLC, a Delaware limited liability company (the "Company"), and Kelly M. Kaplan the ("Employee"), as of the date written below ("the Effective Date").

In connection with the acquisition of the Company by Prestige Brands, Inc., Employee will receive the Consideration (as defined below) as severance and contractual payout. In exchange for the Consideration, Employee intends to fully and unconditionally release any and all claims that he, his heirs, administrators, executors, personal representatives, beneficiaries, and assigns may have against the Company and each of their affiliates, predecessors, successors, subsidiaries, divisions, assigns, officers, directors, members, shareholders, representatives, employees, former employees, attorneys, insurers and agents (collectively referred to as "Releasees"), on the terms contained in this Release as fully set forth below.

1. Consideration. Employee gives the releases, covenants, representations, and warranties stated herein in consideration of the payment of REDACTED, less applicable withholding taxes in severance, and REDACTED in contractual payout, ("the Consideration") to Employee by the Company, to be made by check made payable to Employee and to be delivered to Employee, upon the Effective Date. Additionally, Company will provide health and dental insurance for a period of three months from the Effective Date

2. General Release and Covenants by Employee.

a. Employee does hereby voluntarily and unconditionally remise, release, acquit, and forever discharge the Company and all subsidiary, parent, affiliated or related companies and their respective divisions and their respective past and present officers, directors, members, managers, agents, employees, successors and assigns, in their individual and representative capacities (the "Released Parties"), of and from any and all suits, actions, causes of action, obligations, damages, charges, costs, claims, demands, liabilities, expenses and attorneys' fees of whatever kind of nature, contingent or fixed, liquidated or unliquidated, matured or unmatured, known or unknown, which the Employee, his assigns, heirs and legal representatives may now have, or have ever had, against any or all of the Released Parties, whether or not arising from the Employee's employment relationship with Employer, or which may be related in any way to the Employee's employment relationship with the Company, the termination of that relationship, and/or any other employment related dealings of any kind between on the one hand, and any or all of the Released Parties on the other, which have transpired on, or prior to, the Effective Date, including, but not limited to, any and all claims, rights, demands and causes of action for breach of the covenant of good faith and fair dealing; inducement of breach; wrongful or unlawful discharge; intentional or negligent infliction of emotional distress; intentional or negligent fraud or misrepresentation; conspiracy; failure to pay wages, benefits, severance, or other compensation of any sort; discrimination on the basis of race, color, sex, national origin, religion, age, disability, marital status, sexual orientation, or sexual harassment; retaliation for protesting discrimination on the

basis of race, color, sex, national origin, religion, age, disability, marital status, sexual orientation, or sexual harassment; a violation of any laws, statutes, rules or regulations whether state, federal or local, including, but not limited to, the Americans with Disabilities Act, the National Labor Relations Act, the Fair Labor Standards Act and any other federal, state or local wage, wage hour or wage payment law, the Employee Retirement Income Security Act of 1974 ("ERISA") including but not limited to, breach of fiduciary duty and equitable claims arising under section 1132(a)(3) of ERISA, Title VII of the Civil Rights Act of 1964, the Vocational Rehabilitation Act of 1973, the Age Discrimination in Employment Act of 1990, the Civil Rights Acts of 1866, 1871, 1991, including Section 1981 of the Civil Rights Act, the Family and Medical Leave Act, the Worker Adjustment and Retraining Notification Act (all as amended).

b. The claims, causes of action, security interests, liabilities, and judgments released in Paragraph 2(a) above shall be referred to collectively herein as "Employee's Released Claims."

c. Nothing herein is intended, nor shall it be construed, as a waiver or release by the Employee of his rights, if any, under any statutory claims for state unemployment insurance, worker's compensation, disability insurance benefits (other than discrimination claims for such benefits), and any legal obligations of the Company to indemnify the Employee under applicable by-laws for so long as the Employee adheres to the terms of this Agreement.

d. Employee hereby covenants and agrees that he will forever refrain and forebear from commencing, instituting, or prosecuting any lawsuit, action, or other proceeding against any of the Releasees, individually or collectively, based on, arising out of, or connected with any of Employee's Released Claims.

e. Employee understands and agrees that this Release shall be binding upon him in his individual capacity as well as upon his heirs, administrators, executors, personal representatives, beneficiaries, and assigns.

3. No Assignment or Transfer by Employee of Released Claims. Employee represents and warrants that as of the Effective Date, he has not assigned or transferred, or purported to assign or transfer, to any person, firm, corporation, association, or entity whatsoever, any of Employee's Released Claims. Employee hereby agrees to indemnify and hold harmless Releasees against, without limitation, any and all rights, claims, warranties, demands, debts, obligations, liabilities, costs, expenses (including attorney's fees), causes of action, and judgments based on, arising out of, or connected with any such transfer or assignment, or purported transfer or assignment by Employee. ~~Employee represents and warrants that as of the Effective Date, he has not assigned or transferred, or purported to assign or transfer, to any person, firm, corporation, association, or entity whatsoever, any of Employee's Released Claims.~~ Agreed Sentence KMK 11/14/05

4. Releases Include Unknown Claims. except as set forth herein KMK 11/14/05

a. Employee understands and agrees that Employee's Released Claims are intended to and do include any and all claims of every nature and kind whatsoever (whether known, unknown, suspected, or unsuspected) that Employee may have against the Company.

b. Employee acknowledges that he may hereafter discover facts different from or in addition to those which he now knows or believes to be true with respect to Employee's Released Claims and

agrees that, in such event, this Release shall nevertheless be and remain effective in all respects, notwithstanding such different or additional facts, or the discovery thereof.

c. Employee represents and acknowledges that: (i) he and his attorneys have conducted whatever investigation was deemed necessary by him and his attorneys to ascertain all facts and matters related to this Release; (ii) he has consulted with and received advice from legal counsel concerning this Release; and (iii) he is not relying in any way on any statement or representation by the Company or their attorneys, except as expressly stated herein, in reaching his decision to enter into this Release.

5. No Admission of Liability. The parties understand and agree that this Release does not constitute an admission of liability on the part of the Company as to any matters, whatsoever.

6. Future Legal Actions. In the event either party to this Release commences an action, at law or in equity, to enforce any right under any provision of this Release or to compel compliance with any provision of this Release, Employee, and the Company agree that the prevailing party in any such action shall be entitled to recover from the opposite party all reasonable attorney's fees and costs incurred in connection with such action.

7. Confidential Information. Employee agrees that it will not use, divulge, sell or deliver to or for any other person, firm or corporation other than the Company and its respective subsidiaries, affiliates, successors and assigns any confidential information and material (statistical or otherwise) relating to the Company's business, including, but not limited to, confidential information and material concerning manufacturing, distribution, marketing, sales, advertising, customers, employees, suppliers, licensors, financial information, methods and processes incident to the business, and any other secret or confidential information. On or before the Effective Date, Employee will surrender to the Company all lists, books and records of or in connection with the Company's business and all other property belonging to the Company. Should there be a violation or attempted or threatened violation of this provision, the Company may apply for and obtain an injunction to restrain such violation or attempted or threatened violation, Employee conceding that the loss of such secret or confidential information cannot reasonably or adequately be compensated in damages in an action at law, and that the right to said injunction is necessary for the protection and preservation of the rights of the Company and of any transferee or assignee hereof to prevent irreparable damage to the Company. Such injunctive relief shall be in addition to such other rights and remedies as the Company, and any other permitted transferee or assignee hereof, may have against Employee arising from any breach hereof on his part.

8. Modification. No provision of this Release may be changed, altered, modified or waived except in writing signed by Employee and a duly authorized representative of the Company, which writing shall specifically reference this Release and the provision that the parties intend to waive or modify.

9. Severability. In the event any provision of this Release should be held to be unenforceable, each and all of the other provisions of this Release shall remain in full force and effect.

10. Entire Agreement. The parties hereto acknowledge that this Release constitutes a full, final, and complete settlement of their differences and supersedes and replaces any and all other written or oral exchanges, agreements, understandings, arrangements, or negotiations between or among them relating to the subject matter hereof, and affirmatively state that there are no other prior or contemporaneous agreements, exchanges, representations, arrangements, or understandings, written or oral, between or

among them relating to the subject matter hereof other than that as set forth herein, and that this Release contains the sole and entire Release between them with respect to the subject matter hereof.

11. Understanding. The parties acknowledge and represent that they have read this Release in full and, with advice of counsel, understand and voluntarily consent and agree to each and every provision contained herein.

12. Headings and Captions. The headings and captions used in this Release are for convenience of reference only, and shall in no way define, limit, expand or otherwise affect the meaning or construction of any provision of this Release.

13. Counterparts Acceptable. This Release may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

BY SIGNING BELOW, EMPLOYEE AGREES THAT HE HAS BEEN GIVEN A SUFFICIENT TIME TO READ AND REVIEW THIS RELEASE, THAT HE UNDERSTANDS THIS RELEASE, THAT HE SIGNS IT VOLUNTARILY OF HIS OWN FREE WILL, AND THAT HE IS NOT SUFFERING FROM ANY DISABILITY OR CONDITION THAT WOULD RENDER HIM UNABLE TO ENTER INTO THIS RELEASE.

IN WITNESS WHEREOF, the undersigned have executed this Release on the date shown below.

Kelly M. Kyle Date: 11/14/05

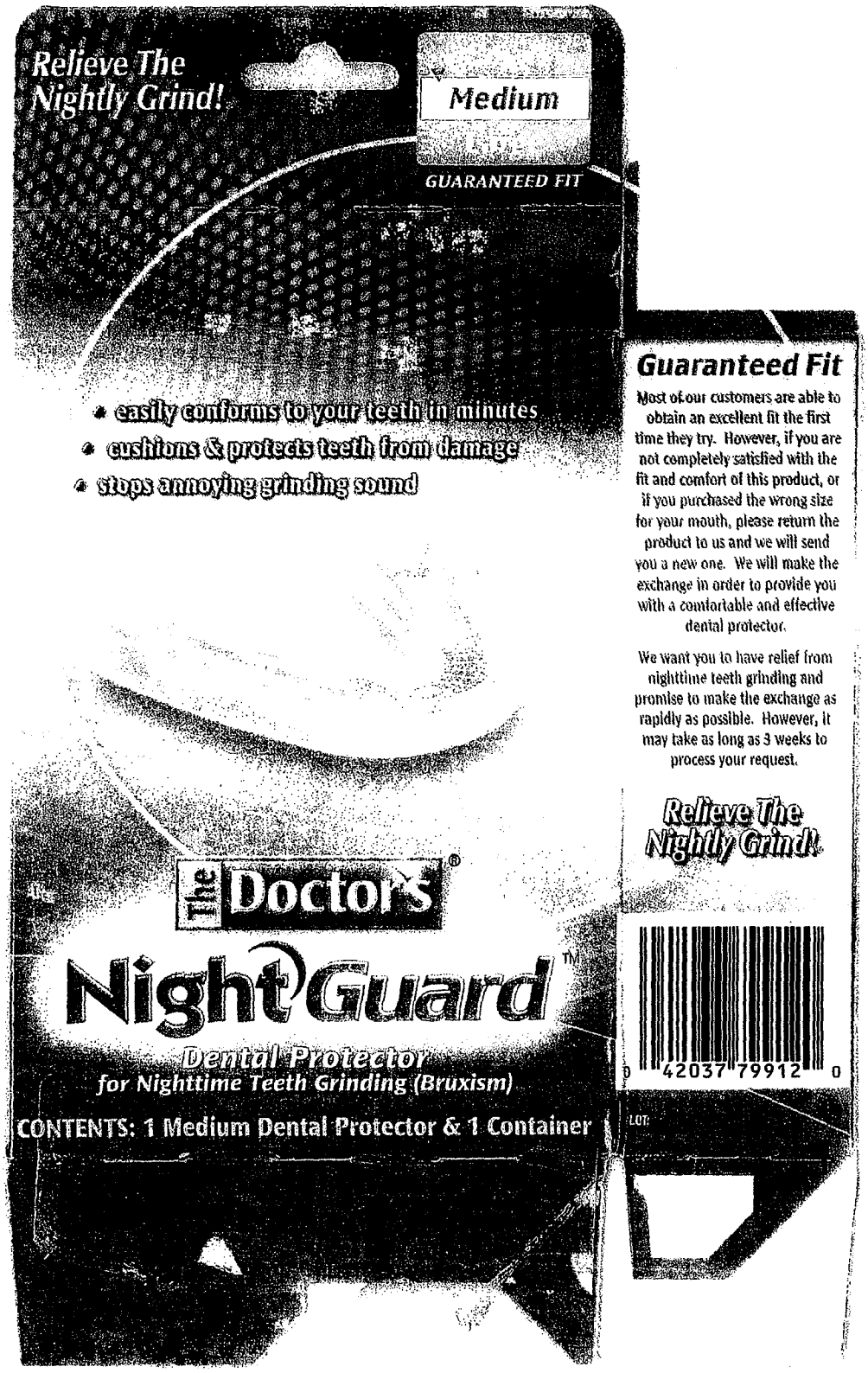
Employee

DENTAL CONCEPTS, LLC

By: _____ Date: 11/14/05

Title: _____

EXHIBIT C


Relieve The Nightly Grind!
Medium
GUARANTEED FIT
easily conforms to your teeth in minutes
cushions & protects teeth from damage
stops annoying grinding sound
The Doctor's
NightGuard™
Dental Protector
for Nighttime Teeth Grinding (Bruxism)
CONTENTS: 1 Medium Dental Protector & 1 Container
Guaranteed Fit
Most of our customers are able to obtain an excellent fit the first time they try. However, if you are not completely satisfied with the fit and comfort of this product, or if you purchased the wrong size for your mouth, please return the product to us and we will send you a new one. We will make the exchange in order to provide you with a comfortable and effective dental protector.
We want you to have relief from nighttime teeth grinding and promise to make the exchange as rapidly as possible. However, it may take as long as 3 weeks to process your request.
Relieve The Nightly Grind!
0 42037 79912 0
LOT:

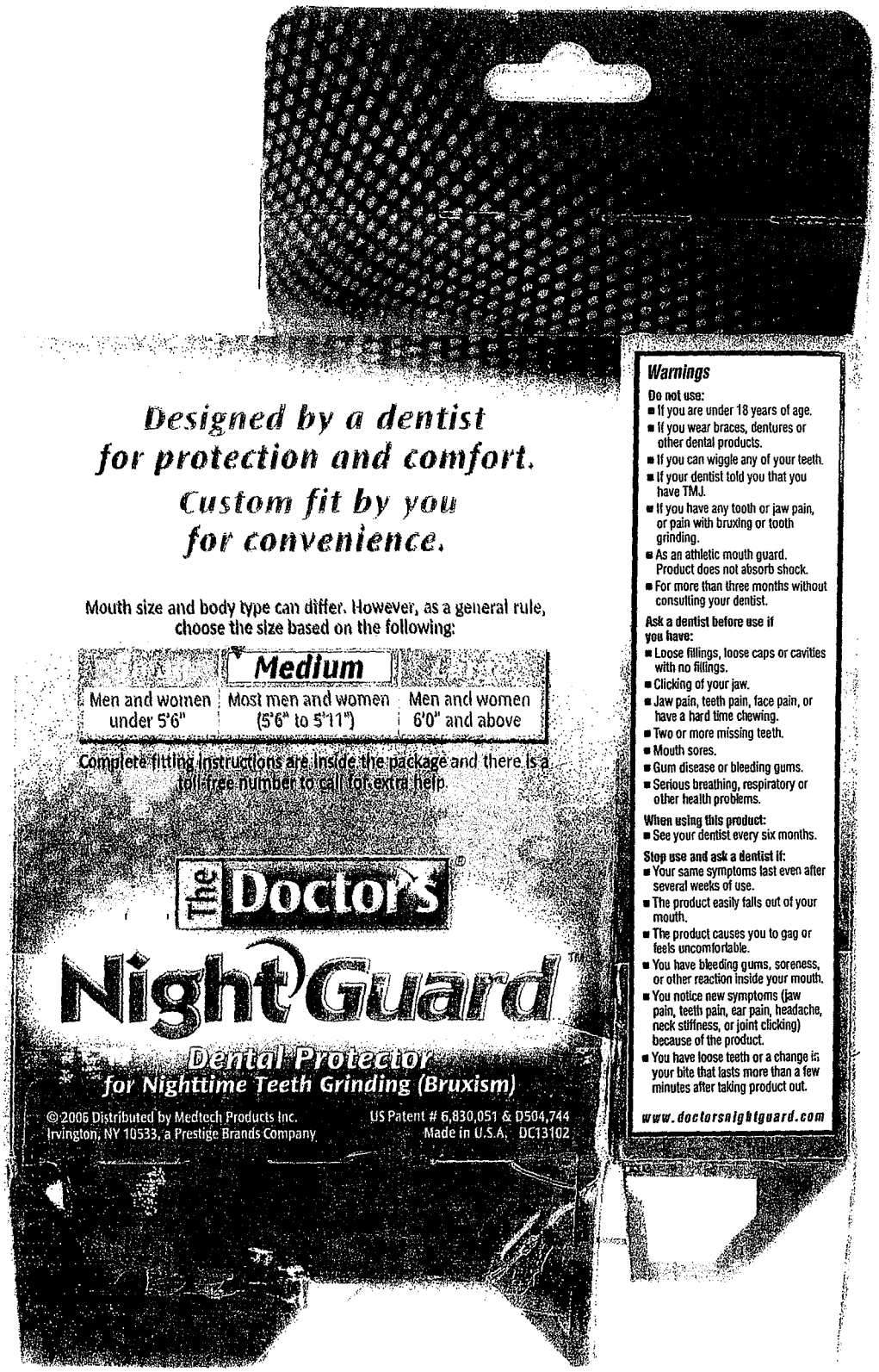

Designed by a dentist
for protection and comfort.
Custom fit by you
for convenience.
Mouth size and body type can differ. However, as a general rule, choose the size based on the following:
Medium
Men and women under 5'6"
Most men and women (5'6" to 5'11")
Men and women 6'0" and above
Complete fitting instructions are inside the package and there is a toll-free number to call for extra help.
The Doctor's
NightGuard™
Dental Protector
for Nighttime Teeth Grinding (Bruxism)
© 2006 Distributed by Medtech Products Inc.
Irvington, NY 10533, a Prestige Brands Company
US Patent # 6,830,051 & D504,744
Made in U.S.A. DC13102
Warnings
Do not use:
If you are under 18 years of age.
If you wear braces, dentures or other dental products.
If you can wiggle any of your teeth.
If your dentist told you that you have TMJ.
If you have any tooth or jaw pain, or pain with bruxing or tooth grinding.
As an athletic mouth guard. Product does not absorb shock.
For more than three months without consulting your dentist.
Ask a dentist before use if you have:
Loose fillings, loose caps or cavities with no fillings.
Clicking of your jaw.
Jaw pain, teeth pain, face pain, or have a hard time chewing.
Two or more missing teeth.
Mouth sores.
Gum disease or bleeding gums.
Serious breathing, respiratory or other health problems.
When using this product:
See your dentist every six months.
Stop use and ask a dentist if:
Your same symptoms last even after several weeks of use.
The product easily falls out of your mouth.
The product causes you to gag or feels uncomfortable.
You have bleeding gums, soreness, or other reaction inside your mouth.
You notice new symptoms (jaw pain, teeth pain, ear pain, headache, neck stiffness, or joint clicking) because of the product.
You have loose teeth or a change in your bite that lasts more than a few minutes after taking product out.
www.doctorsnightguard.com

EXHIBIT D

4. Which size of The Doctor's ® NightGuard™ do you intend to wear?
   Small,
   medium or
   large (circle one).

5. How satisfied are you with The Doctor's ® NightGuard™? Would you say that you are
   (a) extremely satisfied,
   (b) very satisfied,
   (c) somewhat satisfied,
   (d) not very satisfied, or
   (e) extremely dissatisfied? (circle one).

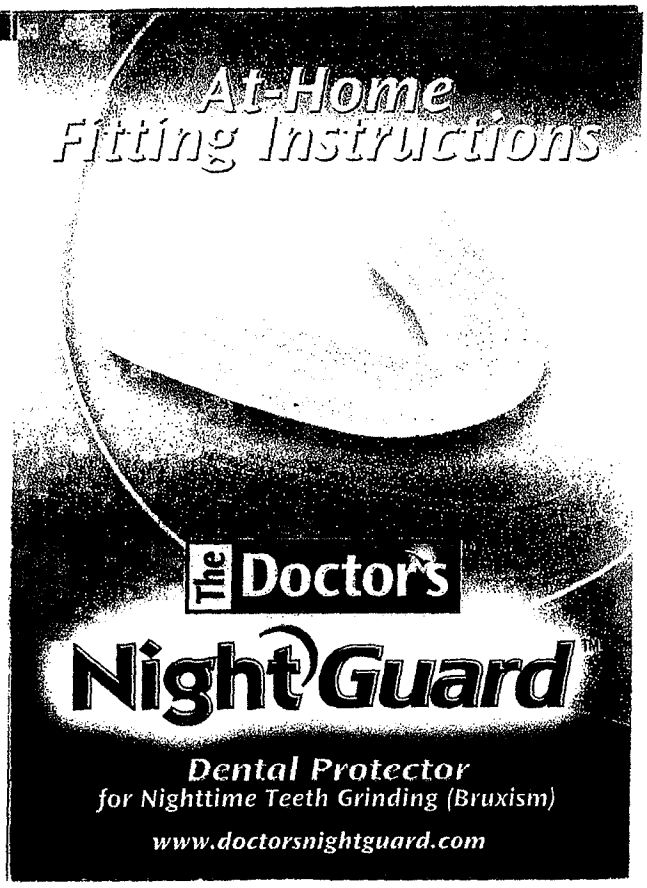
6. What would you do to improve The Doctor's ® NightGuard™?

_____

_____

_____

Thank you for your most valued input!



Use

The Doctor's ® NightGuard™ is indicated for the protection against Bruxism or nighttime teeth grinding. It is intended to reduce damage to teeth and to prevent the noise associated with bruxing or teeth grinding.

The Doctor's ® NightGuard™ is similar to the dental protector recommended by many dentists for nighttime teeth grinding with one advantage: you fit it yourself. After fitting, The Doctor's ® NightGuard™ conforms to your teeth so it will be comfortable. And it will stay in place through the night. By cushioning and keeping the teeth apart, The Doctor's® NightGuard™ reduces the chances for tooth damage; and it stops the annoying grinding sound so your sleep partner will not be disturbed.

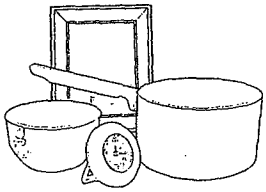
Description

The Doctor's ® NightGuard™ is a moldable dental protector, composed of a soft formable upper material and a hard base. This patented, 2-layered device safely and effectively prevents the noise associated with grinding while cushioning the teeth. When heated by water and then briefly cooled, the upper layer can be molded to fit comfortably around your upper teeth, forming a cushion. The hard base prevents bite-through by consumers with moderate or severe bruxing/grinding. The life of your dental protector will vary based on the force of your teeth grinding. The average dental protector should last six months or more.

For Best Results

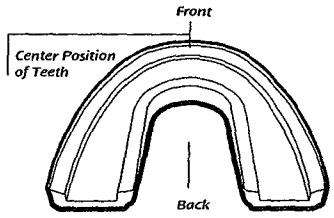
Read and follow instructions BEFORE and DURING custom fitting the dental protector. The dental protector can be fitted on the upper or lower teeth, but upper is preferred.

What You Need to Begin



- A cup of cold water
- A pot to boil water
- A kitchen fork or spoon
- A mirror
- A clock with a second hand to time fitting steps in seconds.

Test Fitting



As soon as you remove the dental protector from the package, and before you begin boiling, conduct a "test fitting."

1. Position The Doctor's ® NightGuard™ in your mouth to determine if you have properly chosen the small, medium or large size. You will know the sizing is correct if your teeth fit comfortably into the channel of the dental protector and if the arms of the U shape reach only to the end of your last molar.
2. If the arch (U-shape) of the dental protector is too narrow or too wide to fit the arch of your mouth, the dental protector can be altered during the final fitting.
3. If the length of the dental protector extends beyond your back molars in the test fitting, the dental protector can be shortened by using a single-edge razor blade or a sharp knife.

Final Fitting

After completing the test fitting, you are now ready to custom fit the dental protector.

Fill a pot with approximately three inches of water. Boil water until you see a rolling boil and bubbles. Let the water boil for one minute before inserting the dental protector into the water.

2. Submerge the dental protector into the boiling water for 60 seconds.
3. Using a fork or spoon, remove the dental protector from the boiling water and submerge it into the cup of cold water for one second to remove the heat from the dental protector.
4. Position the dental protector comfortably into your mouth. You can widen or narrow the dental protector at this point in the process by up to ½ inch.
5. Once in place, firmly bite down into the dental protector.
6. Press in along the gum line using equal amounts of pressure on both sides of the "U" shape from the front of the dental protector to the rear molars. Be sure to use your fingers to mold the soft impression material up and around the teeth.
7. Suck in to remove excess moisture and create the suction that will allow the dental protector to stay comfortably in place on your upper teeth.
8. Once you feel you have attained a comfortable fit, remove the dental protector and place into the cup of cold water for another 30 seconds to "set" the mold.

Storage & Maintenance

Proper care of your dental protector will extend its life.

- After each use, simply rinse the dental protector in cool water or mouth wash.
- Store The Doctor's ® NightGuard™ in the container provided when not in use.

Warnings

Do not use:
- If you are under 18 years of age.
- If you wear braces, dentures, or other dental products.
- If you can wiggle any of your teeth.
- If your dentist has told you that you have TMJ.
- If you have any tooth or jaw pain or pain with bruxing or tooth grinding.
- As an athletic mouth guard. Product does not absorb shock.
- For more than three months without consulting your dentist.

Ask a Dentist Before Use If You Have:
- Loose fillings, loose caps or cavities with no fillings.
- Clicking of your jaw.
- Jaw pain, teeth pain, face pain, or have a hard time chewing.
- Two or more missing teeth.
- Mouth sores.
- Gum disease or bleeding gums.
- Serious breathing, respiratory or other health problems.

When Using This Product:
- See your dentist every six months.

Stop Use and Ask a Dentist if:
- Your same symptoms last even after several weeks of use.
- The product easily falls out of your mouth.
- The product causes you to gag or feels uncomfortable.
- You have bleeding gums, soreness, or other reaction inside your mouth.
- You notice new symptoms (jaw pain, teeth pain, ear pain, headache, neck stiffness, or joint clicking) because of the product.
- You have loose teeth or a change in your bite that lasts more than a few minutes after taking product out.

Guaranteed Fit

Most consumers are able to obtain an excellent fit the first time they try. However, if you are not completely satisfied with the fit and comfort of this product, or if you purchased the wrong size for your mouth, please return the product to us and we will send you a new one. We will also "coach" you through the fitting process over the phone if you so desire. Simply complete the attached survey along with the cash register receipt and indicate the size of the needed replacement to:

Source 1 HTMT
1280 Wall Street West
Lyndhurst, NJ 07071
Or call 1-800-592-6661

Help Us Improve Your Experience with The Doctor's ® NightGuard™

In an effort to serve our customers better, we ask that you kindly take a few moments to provide your feedback in the survey below. Or, you may also visit our website at www.doctorsnightguard.com

Name _____

Mailing Address _____

Apt# ____ City _____ State ____ Zip _____

Email address _____

Daytime Phone Number _____

1. How did you first become aware that you grind your teeth? Were you
   (a) told by the dentist,
   (b) told by a person who sleeps nearby,
   (c) experienced discomfort, or
   (d) other _____? (circle one)
2. Prior to this purchase, what if anything did you do about your teeth grinding? Was it
   (a) did nothing,
   (b) wore a dentist fitted guard,
   (c) wore The Doctor's ® NightGuard ™,
   (d) wore an athletic mouth guard, or
   (e) other _____? (circle one)
3. Is this your first, second or third+ purchase of The Doctor's ® NightGuard™ (circle one).

EXHIBIT E

US006830051B1

(12) **United States Patent**
Lesniak et al.

(10) **Patent No.: US 6,830,051 B1**
(45) **Date of Patent: Dec. 14, 2004**

(54) **INTEROCCLUSAL APPLIANCE**

(75) Inventors: **Frank Lesniak**, Lansdale, PA (US); **Michael S. Lesser**, Green Brook, NJ (US)

(73) Assignee: **Dental Concepts LLC**, Paramus, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 28 days.

(21) Appl. No.: **10/425,908**

(22) Filed: **Apr. 29, 2003**

(51) **Int. Cl.**[7] **A61C 5/14**
(52) **U.S. Cl.** **128/859**; 128/861; 128/862
(58) **Field of Search** 128/846, 848, 128/859–862; 602/902; 433/6

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,247,844	A		4/1966	Berghash
3,496,936	A		2/1970	Gores
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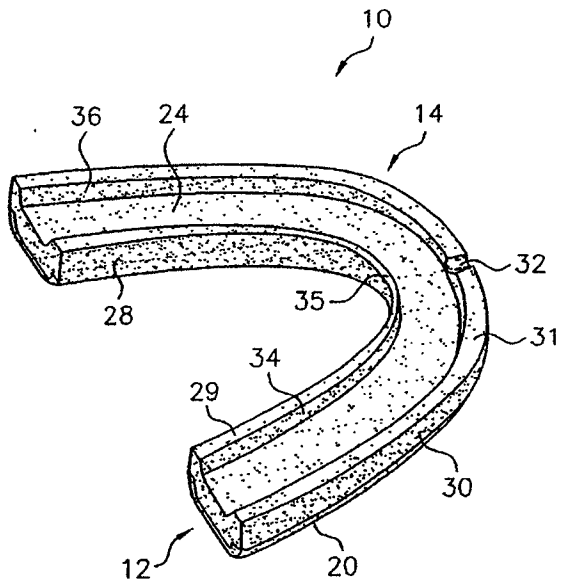
(57) **ABSTRACT**

An interocclusal appliance includes a maxillary impression preform of a resilient thermoplastic having a low softening temperature, e.g. 36° C., such as an EVA copolymer having approximately thirty percent vinyl acetate. The preform is molded over and unitarily bonded to a base having a planar bottom face contacted by mandibular occlusal surfaces. The base is formed of a thermoplastic having a higher softening temperature, e.g. 70° C., with the bond between the preform and base characterized by high shear strength. The preform includes a bight shaped centric relation positioning channel having a thick footing and draft along lingual, buccal and labial walls. The appliance is fitted by immersion in hot water to soften the preform, seating the maxillary arch within the channel and biting, such that the impression of the maxillary dentition embeds in the softened preform. Upon cooling, the preform is transformed into a reusable resilient encasement for the maxillary dentition. Suitable thermoplastics for implementation as the base include an EMA copolymer, blends of EMA and EVA or TPU or blends of TPU and EVA.

17 Claims, 3 Drawing Sheets



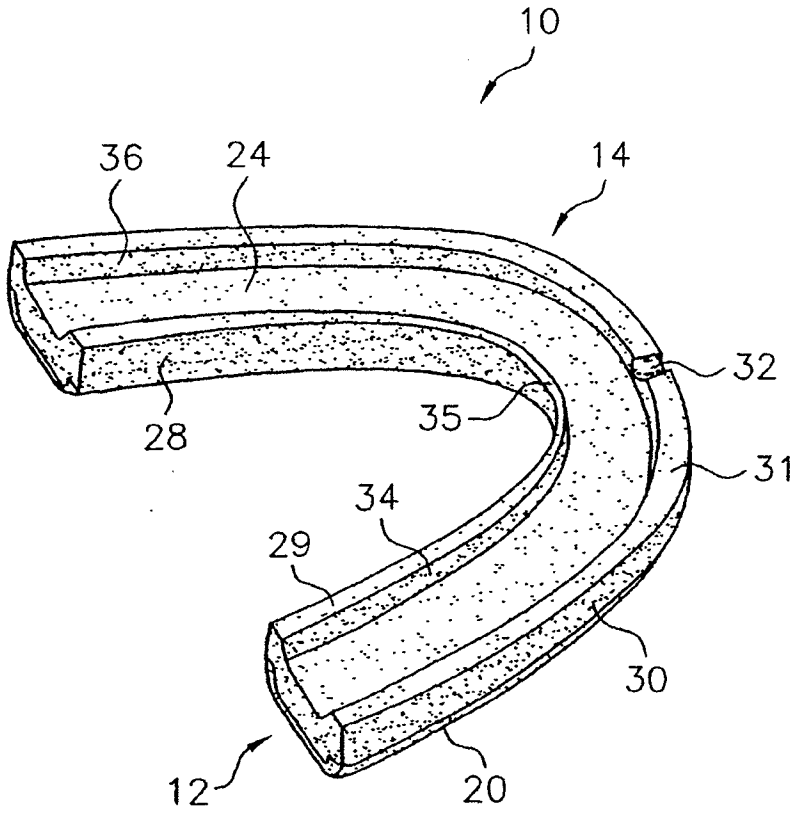


FIG. 1

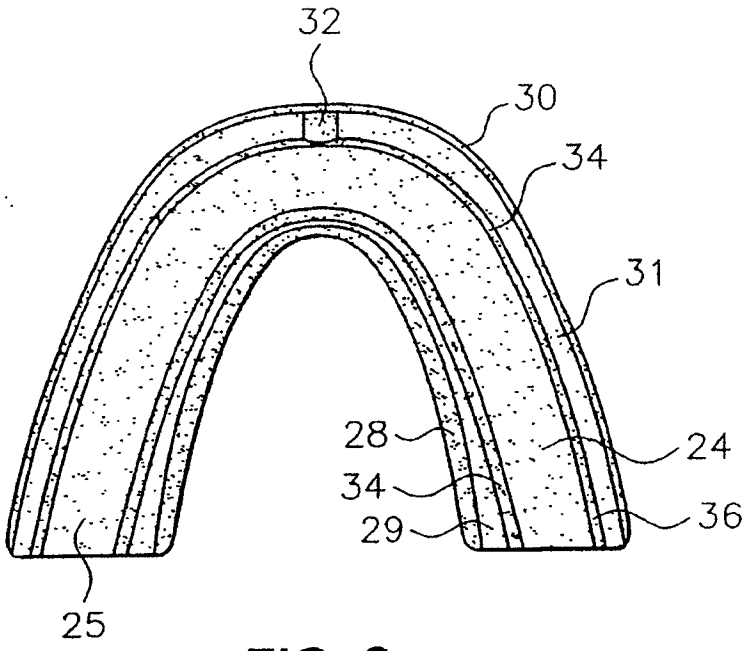


FIG. 2

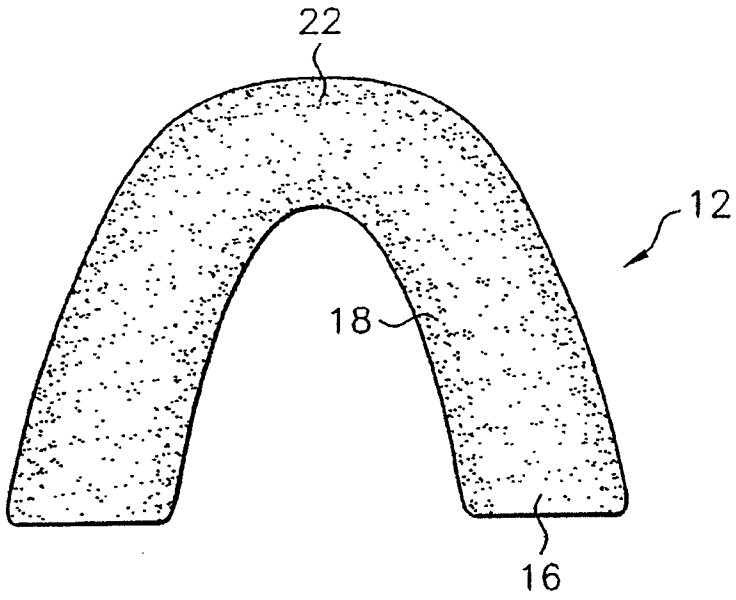


FIG. 3

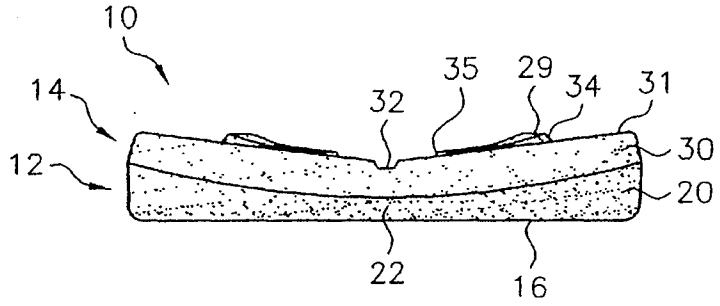


FIG. 4

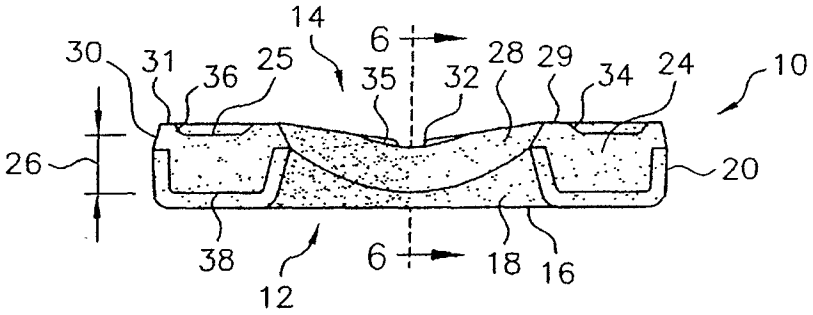


FIG. 5

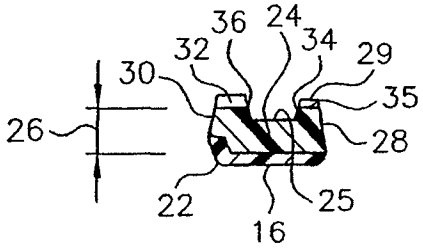


FIG. 6

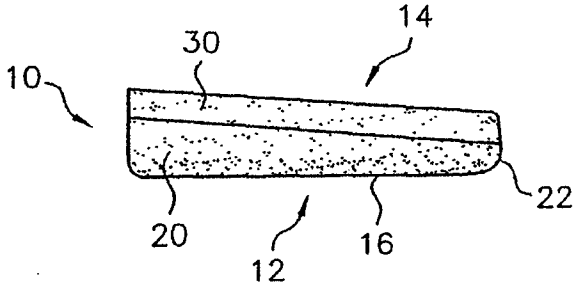


FIG. 7

INTEROCCLUSAL APPLIANCE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to the subconscious parafunctional mandibular habits known as bruxism or clenching and more particularly an interocclusal appliance for the prevention of tooth structure loss resulting therefrom.

2. Antecedents of the Invention

Various studies have been undertaken with respect to the causative factors and precise mechanisms involved in bruxism and clenching. For example, it has been found and that bruxing events could be categorized based on mandibular position patterns.

Studies have also demonstrated that the highest amplitude of nocturnal bite force during bruxism could exceed the amplitude of the maximum voluntary bite force during the daytime. Bruxism and clenching have been found to constitute a major factor in conjunction with occlusal surface wear and constitute a significant potential risk factor for implant failure.

Interocclusal appliances, such as nightguards, have been long recognized as beneficial for the alleviation of the adverse effects of bruxism and clenching.

Prior interocclusal appliances included those fitted by a dental professional and those which were self fitted. Professionally fitted interocclusal appliances were molded of relatively hard acrylic resin from casts of the patient's mouth taken from a dental impression. This procedure was both time consuming and expensive.

A typical self fitted interocclusal appliance included a thermoplastic channel trough in the configuration of a maxillary arch. Carried in the trough was a thermoplastic impressionable liner material having a softening point temperature lower than that of the trough. The liner was molded to conform to the mouth of the user after the appliance was immersed in hot water and then inserted into the mouth, with the liner placed against the maxillary arch. The user's jaw was then closed and biting pressure was applied to force the maxillary teeth into the liner.

Problems which were encountered with respect to self fitting nightguards included those related to the fitting procedure itself and to the durability of the appliance. The inability to properly center and align, i.e. register, the heated impressionable liner material of the nightguard relative to one's own maxillary arch constituted a major deficiency. When the nightguard was not properly registered, an improper fit was obtained, resulting in discomfort as well as premature appliance wear.

Further problems were encountered with respect to the structural integrity of self fitting nightguards. As a result of the shear forces which were generated during bruxing or clenching events, separation of the bond between the liner and the trough occurred. With the trough in contact with the mandibular occlusal surfaces and the maxillary teeth embedded in the liner, lateral, superior and anterior mandibular deviations during bruxing events resulted in shear stress which separated the liner from the trough, rendering the appliance unserviceable.

SUMMARY OF THE INVENTION

A self fitting interocclusal appliance includes a base having a generally planar, smooth, occlusal face and a pair of parallel curved side walls. The base is molded of a thermoplastic having a Vicat softening temperature of at least 65° C. and a Shore A hardness of at least 80.

Molded into the base between and above the side walls is an impression preform comprising an EVA copolymer having approximately thirty percent vinyl acetate, a Vicat softening temperature of approximately 36° C. and a Shore A hardness below 80.

The preform includes a thick footing having a planar upper face and a shallow bight shaped centric relation pilot channel defined by peripheral walls which are sloped downwardly and inwardly from an elevation above the side walls of the base. The upper face of the footing defines the bottom of the pilot channel.

The base and preform are bonded to form a unitary appliance which is fitted by immersion in hot water such that the preform copolymer reaches a temperature above its softening temperature yet which can be comfortably withstood by oral tissue. The appliance is thereafter inserted in the oral cavity with the centric relation pilot channel substantially registered with the teeth of the maxillary arch. Light pressure is applied to seat the maxillary occlusal surfaces in the shallow preform pilot channel, after which biting pressure is applied to imbed the maxillary teeth in the preform footing.

Since the softening temperature of the base thermoplastic was not attained during the heating step, significant deformation of the base is avoided and the upper and lower occlusal surfaces are separated by at least the thickness of the base.

Upon cooling to oral cavity temperature, the preform is transformed into a reusable resilient flexible encasement for the maxillary dentition (maxillary encasement), with the appliance to be removed during day time hours and reused at bed time.

Suitable thermoplastics for employment as the preform include ELVAX® EVA copolymer and suitable thermoplastics for employment as the base include ELVALOY® EMA copolymer, ELVALOY® EMA blended with ELVAX® EVA or ELVALOY® EMA blended with PELLETHANE® TPU elastomer.

From the foregoing compendium, it will be appreciated that it is an aspect of the present invention to provide an interocclusal appliance of the general character described which is not subject to the disadvantages of the antecedents of the invention aforementioned.

A feature of the present invention is to provide an interocclusal appliance of the general character described which is particularly well adapted for self fitting.

It is a consideration of the present invention to provide an interocclusal appliance of the general character described which is well-suited for economical mass production fabrication.

Another aspect of the present invention is to provide an interocclusal appliance of the general character described which is configured for accurate centric relation self fitting.

A further feature of the present invention is to provide an interocclusal appliance of the general character described which reduces stresses imposed on tooth surfaces during bruxing events.

Another consideration of the present invention is to provide an interocclusal appliance of the general character described which is safe and easy to use.

Yet another aspect of the present invention is to provide an interocclusal appliance of the general character described suited for extended usage without deterioration.

To provide an interocclusal appliance of the general character described having a base and an impression material unitarily molded thereto and characterized by a high shear resistance bond between components is a still further consideration of the present invention.

Another feature of the present invention is to provide an interocclusal appliance of the general character described which prevents loss of tooth structure otherwise resulting from bruxing events.

Another aspect of the present invention is to provide an interocclusal appliance of the general character described which is uninhibiting and comfortable to wear.

To provide an interocclusal appliance of the general character described which reduces compressive and lateral forces upon individual tooth surfaces occurring during bruxing events is a still further consideration of the present invention.

A further feature of the present invention is to provide an interocclusal appliance of the general character described which promotes restful sleep.

Further aspects, features and considerations of the present invention in part will be obvious and in part will be pointed out hereinafter.

With these ends in view, the invention finds embodiment in the various combinations of elements, arrangements of parts and series of steps by which the aforesaid aspects, features and considerations and certain other aspects, features and considerations are attained, all with reference to the accompanying drawings and the scope of which will be more particularly pointed out and indicated in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings in which is shown some of the various exemplary embodiments of the invention,

FIG. **1** is a perspective illustration of an interocclusal appliance constructed in accordance with and embodying the invention showing an impression preform having a shallow pilot channel molded over a base,

FIG. **2** is a top plan view of the interocclusal appliance, illustrating the impression preform,

FIG. **3** is a bottom view of the appliance, showing a smooth occlusal face of the base,

FIG. **4** is a front elevational view of the interocclusal appliance, illustrating a labial face of the base and a buccal peripheral wall of the impression preform,

FIG. **5** is a rear elevational view of the interocclusal appliance, illustrating a tapered lingual side wall of the base,

FIG. **6** is a sectional view through the interocclusal appliance, the same being taken substantially along the line **6—6** of FIG. **5**, and

FIG. **7** is a side elevational view of the appliance, showing a downwardly, forwardly sloped buccal side wall of the base and a buccal peripheral wall of the preform.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in detail to the drawings, the reference numeral **10** denotes generally an interocclusal appliance constructed in accordance with and embodying the invention. The appliance **10** includes a lower base **12** having a plan configuration in the general shape of a maxillary dental arch. Molded to the base **12** is an impression preform **14**. The impression preform **14** is transformed into a maxillary dentition encasement during self-fitting of the interocclusal appliance **10**.

The base **12** is substantially of uniform thickness throughout, e.g. 2 mm, and includes a generally planar occlusal face **16**, an upwardly outwardly tapered lingual side wall **18** and a buccal side wall **20**. The buccal side wall **20** slopes downwardly from the rear of the appliance toward its labial face **22** as shown in FIG. 7.

Pursuant to the invention, the impression preform **14** includes a shallow, e.g. between 2 and 2 mm deep, bight shaped centric relation pilot channel **24** configured to facilitate emplacement of the teeth of the user's maxillary arch at optimal position during and throughout self fitting of the appliance. The pilot channel includes a planar face **25**. A footing having a height **26** extends from a horizontal upper surface of the base **12** to the channel face **25**.

The shallow pilot channel **24** is defined by the face **25** and a pair of upwardly extending peripheral walls, i.e. a lingual peripheral wall **28**, having an upper ridge **29**, and a buccal peripheral wall **30**, having an upper ridge **31**. The buccal peripheral wall **30** includes a labial notch **32**. The height of the buccal peripheral wall **30** above the face **25** is approximately between 2 and 2½ mm and is substantially uniform throughout (except at the notch **32**). The height of the lingual peripheral wall is approximately 2 mm at the rear of the pilot channel and approximately 1 mm at a middle reduced height section **35**.

It should be noted that the exterior surfaces of the lingual channel peripheral wall **28** and the buccal channel peripheral wall **30** are upwardly inwardly sloped from the top edge of the base side walls **18, 20**. Similarly, an inner face **34** of the channel peripheral wall **28** and an inner face **36** of the channel peripheral wall **30** taper or slope at a draft angle from their respective ridges **29, 31**, to the face **25** to facilitate self placement and registration of the maxillary teeth in the shallow pilot channel **24**. The width of the channel face between the peripheral walls **28, 30** is approximately 9 mm. at the ends of the channel and approximately 6 mm. at its center. It should be understood that the dimensions herein are merely exemplary and differently sized appliances are appropriate, depending upon the dimensions of the user's dentition.

It should also be noted that the lingual side wall **18** of the base tapers downwardly, toward the front of the appliance, where it meets the upper surface of the base, as can be more readily seen in FIG. **5** and FIG. **6**.

The upper surface of the base and the opposed inner surfaces of the side walls **18, 20**, all of which are bonded to the impression preform **14** when the preform is molded over the base, is designated by the reference numeral **38** in FIG. **5**.

The height **26** of the preform footing varies from a maximum height, shown in FIG. **5** at the rear of the appliance, e.g. 6 to 6½ mm to a minimum height of approximately 4 mm at the front center of the appliance as shown in FIG. **6**. The preform footing constitutes the primary source of impressionable material which forms around and conforms to the shape of the maxillary dentition during self-fitting.

It is significant that the thermoplastic material selected for the base has a softening temperature sufficiently above that of the impression preform material such that the thickness of the base is not significantly reduced as a result of the compressive forces applied during fitting.

Rheological characteristics of the base thermoplastic include a Vicat softening temperature (ASTM D1525) of at least 65° C., which is well above the temperatures reached during the fitting procedure, e.g. 40° C. to 46° C.

The mold bond between the base and the impression preform 14 (which is transformed into the maxillary encasement) is required to withstand the lateral and compressive stresses encountered during bruxing or clenching events at oral cavity temperatures.

In accordance with the present invention, the base 12 is formed by injection molding a thermoplastic resin having requisite characteristics into a base mold cavity. The molded base 12 is positioned in an occlusal appliance mold cavity and a thermoplastic resin having the requisite characteristics for the impression preform 14 is injected into the appliance mold cavity over the base 12 and unitarily bonds thereto.

Suitable resins for employment as the impression preform include an ethylene vinyl acetate (EVA) copolymer available from the Du Pont under the trademark ELVAX® having a vinyl acetate content of at least 25%. A preferred EVA copolymer is ELVAX®150 having a 33% vinyl acetate content by weight, a Vicat softening temperature of 36° C. and a Shore A hardness of 73.

Preferred embodiments of the invention may be fabricated in accordance with the following examples:

EXAMPLE No. 1

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY ® 1609 AC EMA	100%

The ELVALOY® 1609 AC ethylene methyl acrylate copolymer (available from DuPont) was heated to a recommended molding temperature and injection molded into the base mold cavity. The ELVALOY® 1609 AC EMA copolymer contains approximately 9% by weight acrylate and exhibits a Vicat softening temperature of 70° C. and a Shore A hardness of 97.

The following thermoplastic resin was utilized as the impression preform material:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX ® 150 EVA copolymer	100%

The ELVAX®150 EVA was heated to a recommended molding temperature above its melting point and injection molded into an occlusal appliance mold cavity over the molded base positioned within the mold cavity. The unitary interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and the molded over impression preform, both before and after fitting.

The interocclusal appliance of EXAMPLE No. 1 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

It was noted that due to the compressive forces applied during the fitting procedure, slight base deformation occurred in the nature of minor indentations in the occlusal face 16, however, the base thickness was not compromised, such that a minimum spacing between occlusal surfaces of at least the thickness of the base, e.g.

EXAMPLE No. 2

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
PELLETHANE ® 2103 - 80 AEN TPU elastomer	50%
ELVAX ® 750 EVA	50%

ELVAX®750 EVA comprises an ethylene vinyl acetate copolymer available from DuPont and having a 9% vinyl acetate content by weight and PELLETHANE®2103-80 AEN comprises a thermoplastic polyurethane elastomer available from Dow Chemical Co.

Equal amounts by weight of PELLETHANE®2103-80 AEN and ELVAX®750 were blended by conventional apparatus. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity.

The molded base 12 was positioned in an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX ® 150 EVA	100%

The ELVAX®150 EVA was heated to a recommended molding temperature above its melting point and injection molded into the occlusal appliance mold cavity over the molded base.

The interocclusal appliance was removed from the mold cavity and exhibited a high adhesion bond between the base and the impression preform before and after fitting.

The interocclusal appliance of EXAMPLE No. 2 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Greater base deformation occurred during fitting than in Example 1, however, the base thickness was not compromised and a minimum spacing between occlusal surfaces of at least the thickness of the base, e.g. 2 mm. was maintained.

EXAMPLE No. 3

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY ® 1609 AC EMA	90%
ELVAX ® 750 EVA	10%

Ninety percent (90%) by weight of ELVALOY®1609 AC EMA was blended with ten percent (10%) by weight ELVAX®750 EVA with conventional blending apparatus. The blend was then heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. The molded base 12 exhibited a Shore A hardness of 90.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX ® 150 EVA	100%

The ELVAX®150 EVA was heated to a recommended molding temperature above its melting point and injection molded into the occlusal appliance mold cavity over the molded base.

The interocclusal appliance was removed from the mold cavity and exhibited a high adhesion bond between the base and the impression preform both before and after fitting.

The interocclusal appliance of EXAMPLE No. 3 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Slight base deformation occurred during fitting, somewhat greater than that of the base in EXAMPLE No. 1, however, less than the base deformation which occurred in EXAMPLE No. 2.

EXAMPLE No. 4

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY ® 1609 AC EMA	75%
ELVAX ® 750 EVA	25%

Seventy five percent (75%) ELVALOY®1609 AC EMA by weight is blended with 25% by weight ELVAX®750 EVA, utilizing conventional mixing apparatus. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. The molded base 12 exhibited a Shore A hardness of 92.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX ® 150 EVA	100%

The ELVAX®150 EVA preform resin was heated to a suitable molding temperature and injection molded into an occlusal mold appliance cavity after the molded base had been positioned in the cavity. The interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and the molded over impression preform, both before and after the fitting.

The interocclusal appliance of EXAMPLE No. 4 was heated by immersion in boiling water for approximately 40 seconds, removal from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Slight base deformation occurred during fitting, e.g. approximately the same as occurred with respect to EXAMPLE No. 2. The base thickness was not compromised, however, and a minimum spacing between occlusal services of at least the thickness of the base was maintained.

EXAMPLE No. 5

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY ® 1609 AC EMA	50%
ELVAX ® 750 EVA	50%

Fifty percent (50%) ELVALOY® 1609 AC EMA by weight was blended with fifty percent (50%) by weight ELVAX®750 EVA, utilizing conventional mixing apparatus. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. The molded base 12 exhibited a Shore A hardness of 95.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX ® 150 EVA	100%

The ELVAX®150 EVA preform resin was heated to a suitable molding temperature and injection molded into an occlusal mold appliance cavity after the molded base had been positioned in the cavity. The interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and molded over impression preform, both before and after the fitting.

The interocclusal appliance of EXAMPLE No. 5 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Some deformation of the base occurred during fitting, i.e. greater than the deformation which occurred with respect to EXAMPLE No. 2. The base thickness was not compromised, however, and a minimum spacing between occlusal surfaces of at least the thickness of the base was maintained.

EXAMPLE No. 6

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY ® 1609 AC EMA	90%
PELLETHANE ® 2103-80 AEN TPU	10%

Ninety percent (90%) ELVALOY®1609 AC by weight is blended with ten percent (10%) PELLETHANE®2103-80 AEN. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. Molded base 12 exhibited a Shore A hardness of 95.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX ® 150 EVA	100%

The ELVAX®150 EVA preform resin was heated to a suitable molding temperature and injection molded into an occlusal mold appliance cavity after the molded base had been positioned in the cavity. The interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and molded over impression preform, both before and after the fitting.

The interocclusal appliance of EXAMPLE No. 6 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Slight base deformation occurred during fitting, i.e. less than the deformation which occurred with respect to EXAMPLE No. 1.

Other suitable base resin formulations comprise blends of ELVALOY® 1609 AC EMA and PELLETHANE® 2103-80 AEN TPU ranging between 10% to 50% TPU by weight. Additional base resin formulations may comprise linear low density polyethylene (LLDPE), low density polyethylene (LDPE) or blends of ELVAX 750 EVA and LLDPE or LDPE with the LLDPE or LDPE content ranging from 25% to 90% by weight.

It should be appreciated that the foregoing is merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention. The principal rheological and other attributes of the selected resins include a suitable softening temperature range for the impression preform resin which will not create temperature induced discomfort or damage to oral tissue, a softening temperature range and hardness of the base resin such that substantial deformation of the base does not occur during fitting and over prolonged usage.

An additional and significant characteristic upon which the selection of resins is predicated is the ability to obtain a unitary molded over bond between the base and the preform/maxillary dentition encasement which is well-suited to withstand the high shear and compression forces generated during bruxing and clenching events.

In this regard, it should be noted that in the foregoing examples, the surface 38 of the base over which the impression preform resin is molded may include a coating of a bonding agent or priming material or may be textured to augment the bond, all within the context of the present invention.

Also within the purview of the invention is the utilization of the interocclusal appliance in an inverted state, that is having the occlusal face 16 of the base in contact with maxillary occlusal surfaces and the mandibular dentition impressed in the impression preform.

Thus it will be seen that there is provided an interocclusal appliance which achieves the various aspects, features and considerations of the present invention and which is well-suited to meet the conditions of practical usage.

Since various possible embodiments might be made of the present invention and since various changes might be made in the exemplary embodiments shown herein, without departing from the spirit of the invention, it should be understood that all matter herein described or shown in the accompanying drawings should be interpreted as illustrative and not in a limiting sense.

Having thus described the invention there is claimed as new and desired to be secured by Letters Patent:

1. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the appliance comprising a base and an impression preform unitarily bonded thereto, the base having a plan configuration of a dental arch and a generally planar occlusal face, the impression preform being bonded to an opposite face of the base, the impression preform including a bight shaped shallow centric relation pilot channel, the pilot channel having a generally planar face and a pair of spaced peripheral walls, the impression preform further including a footing having a height extending from the opposite face of the base to the face of the pilot channel, the impression preform comprising a resin having a Shore A hardness below 80 and a Vicat softening temperature, the base comprising a resin having a hardness of at least Shore A 80 and a Vicat softening temperature above that of the impression preform resin.

2. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the impression preform resin comprises an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

3. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 2 wherein the base resin comprises an ethylene methyl acrylate copolymer.

4. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the base resin comprises an ethylene methyl acrylate copolymer.

5. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 4 wherein the ethylene methyl acrylate copolymer includes approximately 9% by weight acrylate.

6. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the base resin comprises a thermoplastic polyurethane elastomer blended with an ethylene vinyl acetate copolymer.

7. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the base resin comprises an ethylene methyl acrylate copolymer blended with a thermoplastic selected from the group consisting of ethylene vinyl acetate copolymer and thermoplastic polyurethane elastomer.

8. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the pilot channel has a depth in the order of 2 mm.

9. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein each peripheral wall includes a ridge and an inner face, the inner faces being sloped downwardly and inwardly from their respective ridges toward the face of the pilot channel.

10. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the face of the pilot channel is between approximately 6 mm to 9 mm wide.

11. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the height of the footing ranges from approximately 4 mm at the center of the pilot channel to at least 6½ mm at the rear of the pilot channel.

12. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the height of the footing is at least twice the distance between the occlusal face of the base and the opposite face of the base.

13. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the appliance comprising a base and an impression preform unitarily bonded thereto, the base having a plan configuration of a dental arch and a generally planar occlusal face, the impression preform being bonded to an opposite face of the base, the impression preform including a bight shaped shallow centric relation pilot channel, the pilot channel having a generally planar face and a pair of spaced peripheral walls, the impression preform further including a footing having a height extending from the opposite face of the base to the face of the pilot channel, the height of the footing being at least twice the distance between the occlusal face of the base and the opposite face of the base.

14. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 13 wherein the impression preform comprises an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate and the base comprises an ethylene methyl acrylate copolymer having approximately 9% by weight acrylate and a Vicat softening temperature of at least 70° C.

15. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 13 wherein the pilot channel has a depth which is approximately the distance between the occlusal face of the base and the opposite face of the base.

16. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 13 wherein the channel width is approximately 4 times the distance between the occlusal face of the base and the opposite face of the base.

17. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the method comprising the steps of:

a) molding and appliance base from a resin having a Vicat softening temperature of at least 70° C. and a Shore A hardness of at least 80; and

b) molding over the base an impression preform from a resin comprising an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

* * * * *

EXHIBIT F

Certificate of Registration

This Certificate issued under the seal of the Copyright Office in accordance with title 17, United States Code, attests that registration has been made for the work identified below. The information on this certificate has been made a part of the Copyright Office records.

Marybeth Peters

Register of Copyrights, United States of America

Form TX
For a Nondramatic Literary Work
UNITED STATES COPYRIGHT OFFICE

TX 6-536-309

EFFECTIVE DATE OF REGISTRATION
4 13 2007
Month Day Year

DO NOT WRITE ABOVE THIS LINE. IF YOU NEED MORE SPACE, USE A SEPARATE CONTINUATION SHEET.

1 TITLE OF THIS WORK ▼

The Doctor's® NightGuard™

PREVIOUS OR ALTERNATIVE TITLES ▼

PUBLICATION AS A CONTRIBUTION If this work was published as a contribution to a periodical, serial, or collection, give information about the collective work in which the contribution appeared. Title of Collective Work ▼

If published in a periodical or serial give: Volume ▼ Number ▼ Issue Date ▼ On Pages ▼

2 a NAME OF AUTHOR ▼ — DATES OF BIRTH AND DEATH Year Born ▼ Year Died ▼

Medtech Products Inc.

Was this contribution to the work a "work made for hire"? ☑ Yes ☐ No

AUTHOR'S NATIONALITY OR DOMICILE Name of Country OR Citizen of ▶ USA Domiciled in ▶

WAS THIS AUTHOR'S CONTRIBUTION TO THE WORK Anonymous? ☐ Yes ☑ No Pseudonymous? ☐ Yes ☑ No If the answer to either of these questions is "Yes," see detailed instructions.

NATURE OF AUTHORSHIP Briefly describe nature of material created by this author in which copyright is claimed. ▼

NOTE Under the law, the "author" of a "work made for hire" is generally the employer, not the employee (see instructions). For any part of this work that was "made for hire" check "Yes" in the space provided, give the employer (or other person for whom the work was prepared) as "Author" of that part, and leave the space for dates of birth and death blank.

b NAME OF AUTHOR ▼ — DATES OF BIRTH AND DEATH Year Born ▼ Year Died ▼

Was this contribution to the work a "work made for hire"? ☐ Yes ☐ No

AUTHOR'S NATIONALITY OR DOMICILE Name of Country OR Citizen of ▶ Domiciled in ▶

WAS THIS AUTHOR'S CONTRIBUTION TO THE WORK Anonymous? ☐ Yes ☐ No Pseudonymous? ☐ Yes ☐ No If the answer to either of these questions is "Yes," see detailed instructions.

NATURE OF AUTHORSHIP Briefly describe nature of material created by this author in which copyright is claimed. ▼

c NAME OF AUTHOR ▼ — DATES OF BIRTH AND DEATH Year Born ▼ Year Died ▼

Was this contribution to the work a "work made for hire"? ☐ Yes ☐ No

AUTHOR'S NATIONALITY OR DOMICILE Name of Country OR Citizen of ▶ Domiciled in ▶

WAS THIS AUTHOR'S CONTRIBUTION TO THE WORK Anonymous? ☐ Yes ☐ No Pseudonymous? ☐ Yes ☐ No If the answer to either of these questions is "Yes," see detailed instructions.

NATURE OF AUTHORSHIP Briefly describe nature of material created by this author in which copyright is claimed. ▼

3 a YEAR IN WHICH CREATION OF THIS WORK WAS COMPLETED This information must be given in all cases. 2006 ◀ Year

b DATE AND NATION OF FIRST PUBLICATION OF THIS PARTICULAR WORK Complete this information ONLY if this work has been published. Month ▶ 09 Day ▶ 28 Year ▶ 2006 ◀ Nation USA

4 COPYRIGHT CLAIMANT(S) Name and address must be given even if the claimant is the same as the author given in space 2. ▼

Medtech Products Inc.
90 North Broadway, Irvington, New York 01533

See instructions before completing this space.

TRANSFER If the claimant(s) named here in space 4 is (are) different from the author(s) named in space 2, give a brief statement of how the claimant(s) obtained ownership of the copyright. ▼

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APR 13 2007

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MORE ON BACK ▶ • Complete all applicable spaces (numbers 5-9) on the reverse side of this page. • See detailed instructions. • Sign the form at line 8.

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Page 1 of ..... pages

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FOR COPYRIGHT OFFICE USE ONLY

DO NOT WRITE ABOVE THIS LINE. IF YOU NEED MORE SPACE, USE A SEPARATE CONTINUATION SHEET.

PREVIOUS REGISTRATION Has registration for this work, or for an earlier version of this work, already been made in the Copyright Office? 5

☐ Yes ☒ No If your answer is "Yes," why is another registration being sought? (Check appropriate box.) ▼

a. ☐ This is the first published edition of a work previously registered in unpublished form.

b. ☐ This is the first application submitted by this author as copyright claimant.

c. ☐ This is a changed version of the work, as shown by space 6 on this application.

If your answer is "Yes," give: Previous Registration Number ▶ Year of Registration ▶

DERIVATIVE WORK OR COMPILATION 6

Preexisting Material Identify any preexisting work or works that this work is based on or incorporates. ▼ a

Material Added to This Work Give a brief, general statement of the material that has been added to this work and in which copyright is claimed. ▼ b

See instructions before completing this space

DEPOSIT ACCOUNT If the registration fee is to be charged to a Deposit Account established in the Copyright Office, give name and number of Account. 7

Name ▼ Account Number ▼ a

CORRESPONDENCE Give name and address to which correspondence about this application should be sent. Name/Address/Apt/City/State/Zip ▼ b

Area code and daytime telephone number ▶ Fax number ▶

Email ▶

CERTIFICATION* I, the undersigned, hereby certify that I am the 8

Check only one ▶
- ☐ author
- ☐ other copyright claimant
- ☐ owner of exclusive right(s)
- ☒ authorized agent of Medtech Products Inc.

Name of author or other copyright claimant, or owner of exclusive right(s) ▲

of the work identified in this application and that the statements made by me in this application are correct to the best of my knowledge.

Typed or printed name and date ▼ If this application gives a date of publication in space 3, do not sign and submit it before that date.

Micheline Kelly Johnson Date ▶ March 20, 2007

Handwritten signature ▼

Micheline Kelly Johnson

Certificate will be mailed in window envelope to this address: 9

Name ▼
Micheline Johnson: Baker, Donelson, Bearman, Caldwell & Berkowitz

Number/Street/Apt ▼
633 Chestnut St., 1800 Republic Centre

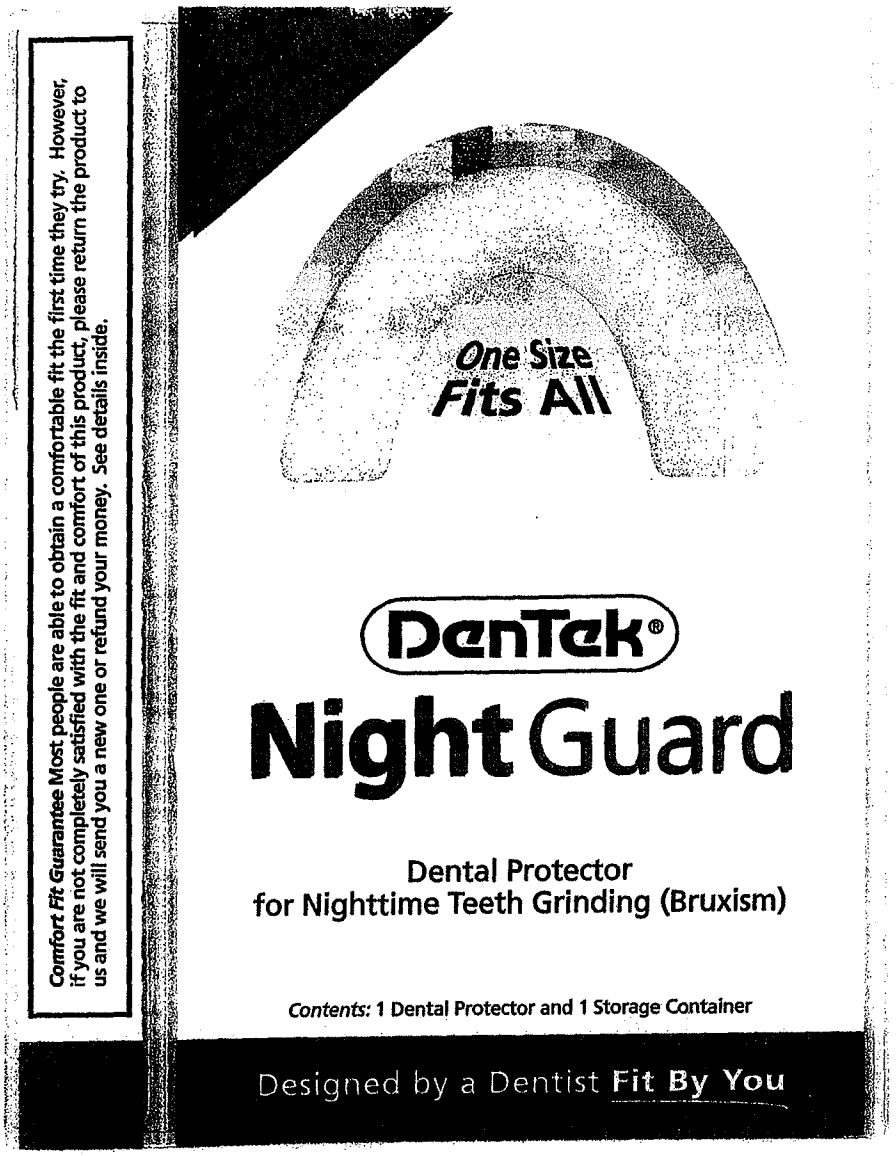
City/State/Zip ▼
Chattanooga, TN 37450-1800

*17 USC §506(e): Any person who knowingly makes a false representation of a material fact in the application for copyright registration provided for by section 408, or in any written statement filed in connection with the application, shall be fined not more than $2,500.

Form TX – Rev. 11/2002 Printed on recycled paper U.S. Government Printing Office: 2002—491,164

TOTAL P.03

EXHIBIT G


Comfort Fit Guarantee Most people are able to obtain a comfortable fit the first time they try. However, if you are not completely satisfied with the fit and comfort of this product, please return the product to us and we will send you a new one or refund your money. See details inside.
One Size Fits All
DenTek®
Night Guard
Dental Protector
for Nighttime Teeth Grinding (Bruxism)
Contents: 1 Dental Protector and 1 Storage Container
Designed by a Dentist Fit By You

DenTek®

Night Guard

Dental Protector
for Nighttime Teeth Grinding (Bruxism)

- Molds To Your Teeth For A Custom Fit
- Custom Fits: Small, Medium, Large
- Stops Annoying Grinding Sounds

Warnings

Do not use: • If you are under 18 years of age. • If you wear braces, dentures or other dental appliances. • If you can wiggle any of your teeth. • If your dentist has told you that you have TMJ. • If you have any tooth or jaw pain, or pain with bruxing or tooth grinding. • As an athletic mouth guard. Product does not absorb shock. • For more than three months without consulting your dentist.

Ask a dentist before use if you have: • Loose fillings, loose caps or cavities with no fillings. • Clicking of your jaw. • Jaw pain, teeth pain, face pain, or have a hard time chewing. • Two or more missing teeth. • Mouth sores. • Gum disease or bleeding gums. • Serious breathing, respiratory or other health problems.

When using this product: • See your dentist every six months.

Stop use and ask a dentist if: • Your same symptoms last even after several weeks of use. • The product easily falls out of your mouth. • The product causes you to gag or feels uncomfortable. • You have bleeding gums, soreness, or other reaction inside your mouth. • You notice new symptoms (jaw pain, teeth pain, ear pain, headache, neck stiffness, or joint clicking) because of the product. • You have loose teeth or a change in your bite that lasts more than a few minutes after taking the product out.

Complete fitting instructions are inside the package and you can visit our website or call our toll-free number for further assistance.

Questions or Comments
800-4DENTEK (800-433-6835) www.dentekmightguard.com

Patents Pending Manf. for: DenTek Oral Care, Inc. Maryville, TN 37801
 Made in USA 1106-500254

0 47701 00127 1

EXHIBIT H

NEW!

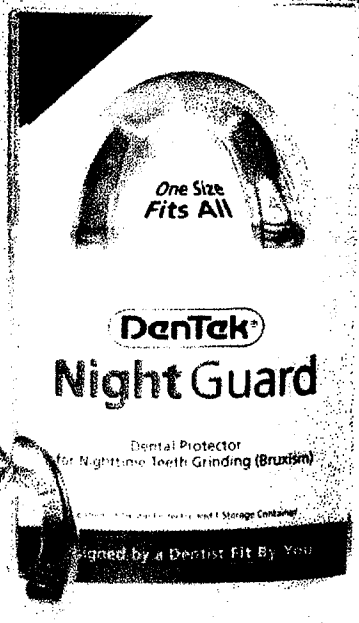
Nighttime teeth grinding shattering your day?

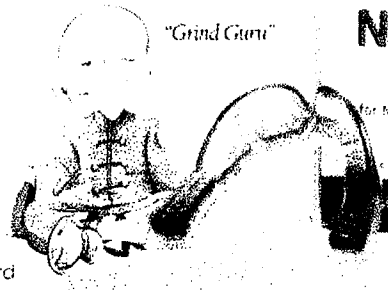
Approximately 1 in 4 people grind their teeth while they sleep and many don't even know they're doing it. If you're waking up with headaches, jaw and muscle pain, or have experienced fractured teeth or even tooth loss, you could be one of the millions of people who suffer the damaging effects of bruxism (teeth grinding).

Support is here...DenTek® NightGuard

With its 100% Custom-fit Guarantee, DenTek® NightGuard will help you to combat the damaging effects of bruxism. You'll protect your teeth while you sleep and awaken more refreshed, ready to take on your day with...a smile.

DenTek® NightGuard. Fits Your Lifestyle.
Now available without a prescription in the dental care aisle.





***Not sure if you grind your teeth?* Find out now.**
Go to www.DenTekNightGuard.com
Visit the Grind Guru to get stress tips and video fitting instructions.

SAVE $3 NOW!
Go to www.DenTekNightGuard.com
for a **valuable coupon** off your purchase of DenTek NightGuard
Enter Promo Code 0601NG01

DenTek® Oral Health for Life

EXHIBIT I

Warnings

Do not use:

- If you are under 18 years of age.
- If you wear braces, dentures or other dental appliances.
- If you can wiggle any of your teeth.
- If your dentist has told you that you have TMJ.
- If you have any tooth or jaw pain, or pain with bruxing or tooth grinding.
- As an athletic mouth guard. *Product does not absorb shock.*
- For more than three months without consulting your dentist.

Ask a dentist before use if you have:

- Loose fillings, loose caps or cavities with no fillings.
- Clicking of your jaw.
- Jaw pain, teeth pain, face pain, or have a hard time chewing.
- Two or more missing teeth.
- Mouth sores.
- Gum disease or bleeding gums.
- Serious breathing, respiratory or other health problems.

When using this product:

- See your dentist every six months.

Stop use and ask a dentist if:

- Your same symptoms last even after several weeks of use.
- The product easily falls out of your mouth.
- The product causes you to gag or feels uncomfortable.
- You have bleeding gums, soreness, or other reaction inside your mouth.
- You notice new symptoms (jaw pain, teeth pain, ear pain, headache, neck stiffness, or joint clicking) because of the product.
- You have loose teeth or a change in your bite that lasts more than a few minutes after taking the product out.

Dental Protector for Nighttime Teeth Grinding (Bruxism)

DenTek®

At-Home Fitting Instructions

Comfort-Fit Guarantee

If you are not completely satisfied with the fit and comfort of this product, we will gladly replace it. If after replacement, you are still not satisfied, we will refund your money (not including taxes and postage costs). To request a replacement or refund, please complete and cut out the form below. Mail the form, product, and original dated register receipt with the correct postage to:

DenTek NightGuard
P.O. Box 49150
Strongsville, OH 44149-0150

Guarantee is valid only if we receive all of the above within 21 days of purchase.

We want you to have relief from nighttime teeth grinding and promise to make the exchange as quickly as possible. However, it may take as long as three weeks to receive your request.

Questions or Comments
800-4dentek (800-433-6835) www.denteknightguard.com

Name: _____

Address: _____

_____

City: _____

State: _____ Zip: _____

Email: _____

Telephone: _____

Reason for Return: _____

All fields required

Visit our website, **www.denteknightguard.com**, and you'll find:

- Animated fitting instructions
- Education on Bruxism and stress relief
- Free offers for other DenTek® products

Use

DenTek® NightGuard is indicated for the protection against Bruxism or nighttime teeth grinding. By cushioning and keeping the teeth apart, DenTek® NightGuard is intended to reduce damage to teeth and to prevent the noise associated with bruxing or teeth grinding.

DenTek® NightGuard is similar to the dental protector recommended by many dentists for nighttime teeth grinding. After fitting, DenTek® NightGuard conforms to your teeth so it is comfortable to wear and stays in your mouth all night.

Description

DenTek® NightGuard is a moldable dental protector specially designed with two materials:

- The blue, formable material, when heated, molds to your upper molars, front teeth, and most of the gum line for optimal retention.
- The harder base material cushions your teeth and prevents bite through from bruxing/grinding.

The life of your custom fit dental protector will vary based on the force of your teeth grinding. The average dental protector should last approximately six months or more.

For Best Results

Read and follow instructions BEFORE and DURING custom fitting the dental protector. The dental protector should be fitted to the upper teeth.

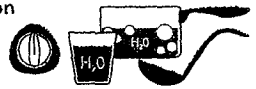
If you need additional assistance, visit our website, or call our customer service department between 8am and 5pm eastern standard time and we will guide you through the fitting process.

www.denteknightguard.com

1-800-4DENTEK

What You Need To Begin

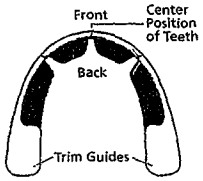
- A cup of room temperature water
- A pot of boiling water
- A metal kitchen spoon
- A timer



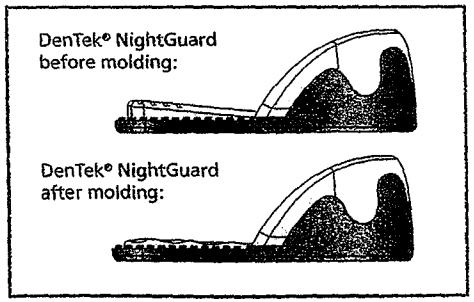
Test Fitting

Before you begin boiling, conduct a "test fitting."

1. Position DenTek® NightGuard in your mouth and bite down. If the arch (U-shape) is too wide or too narrow, squeeze or stretch it to align with the arch of your mouth during the final fitting.



2. If the length of your dental protector extends beyond your last molar and feels uncomfortable, use scissors to cut it along the trim guides. Start at the first line from the end and test fit it again. If that still is not comfortable, cut it again at the second trim line, remembering that it's best if all teeth touch the dental protector. Continue this until the dental protector feels comfortable and all teeth are cushioned. The optimal fit is when all teeth are properly centered and resting on the dental protector.



Final Fitting

After completing the test fitting, you are now ready to custom fit DenTek NightGuard. Make sure you have a cup of room temperature water ready for cooling.

1. Fill a pot with approximately three inches of water. Boil water until you see a rolling boil with bubbles. Remove the pot from the heating element and let rest for one minute.
2. Submerge dental protector face down into hot water for 25 seconds.
3. Remove dental protector with a metal spoon and submerge into cup of room temperature water for one second to reduce the heat before fitting.
4. Position the dental protector in your mouth, aligning it with your teeth, so that all of your teeth rest on the dental protector. You may need to squeeze or stretch the arch of the dental protector to align with the arch of your mouth.
5. Once in place, bite down firmly and suck in to remove excess moisture. Using your fingers, press in along the gum line under your lip with equal amounts of pressure on both sides of the "U" from the front to the rear teeth, molding the soft blue material up and around your teeth and gum line.

If you did not get a good fit the first time, repeat the boiling process one more time starting at Step 1 above. After the second try, the material loses retention and you will need to follow the instructions for a replacement dental protector.

Storage and Maintenance

Proper care of your DenTek® NightGuard will extend its life.

- After each use, rinse the dental protector in cool water or mouthwash. Never use hot water on your dental protector as it might lose its shape.
- Store in the hygienic storage container when not in use.